Practitioner's Docket No. IMPEL.57972

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/EP00/00863	03 February 2000 (3.02.00)	06 February 1999 (6.02.99)
International Application Number	**International Filing Date**	**International Earliest Priority Date**

TITLE OF INVENTION: A DEVICE FOR INTRAVASCULAR CARDIAC VALVE SURGERY

APPLICANT(S): SIESS, Thorsten; FLAMENG, Willem

Box PCT
Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. SECTION 1.10*

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I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date 8/3/2001, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL631726559US, addressed to the: Commissioner for Patents, Washington, D.C. 20231.

Karen Earl
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Karen Earl
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Practitioner's Docket No. IMPEL.57972

1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. Section 371:

   a. This express request to immediately begin national examination procedures (35 U.S.C. Section 371(f)).

   b. The U.S. National Fee (35 U.S.C. Section 371(c)(1)) and other fees (37 C.F.R. Section 1.492) as indicated below:

2. Fees

CLAIMS FEE*	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALC-ULATIONS
	TOTAL CLAIMS	10 -20 =	0	x $18.00 =	$0.00
	INDEPEN-DENT CLAIMS	2 - 3 =	0	x $80.00 =	$0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + $270.00				$0.00
BASIC FEE	U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in Section 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in Section 1.445(a)(2) to the U.S. PTO: where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R Section 1.492(a)(5)) $860.00				$860.00
	Total of above Calculations				= $860.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed. (note 37 CFR Sections 1.9, 1.27, 1.28)				- $430.00
	Subtotal				$430.00
	Total National Fee				$430.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. Section 1.21(h)). See attached "ASSIGNMENT COVER SHEET".				$0.00
TOTAL	Total Fees enclosed				$430.00

*See attached Preliminary Amendment eliminating Multiple Dependencies.

Attached is our check for $430.00

Please charge our Deposit Account No. 21-0800 for any fee deficiencies.

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3. A copy of the Notification of the Communication of the Record Copy of Int'l application to the U.S. (PCT/IB/308).

4. A translation of the International application into the English language (35 U.S.C. Section 371(c)(2)) is transmitted herewith.

5. A translation of the request (PCT/RO/101)

6. An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a) is transmitted herewith.

7 Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. Section 371(c)(3)) were not made.

8. A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. Section 371(c)(3)) has not been transmitted for reasons indicated in section 5.

9. A copy of the international examination report (PCT/IPEA/409) including annexes is transmitted herewith.

10. A translation of IPEA opinion will follow as soon as available.

11. An oath or declaration of the inventor (35 U.S.C. Section 371(c)(4)) complying with 35 U.S.C. Section 115 will follow.

12. International Publication No. WO 00/4587
Front page only

Practitioner's Docket No. IMPEL.57972

II. Other document(s) or information included:

13. Preliminary amendment (37 C.F.R. Section 1.121)

14. An Information Disclosure Statement under 37 C.F.R. Sections 1.97 and 1.98 is transmitted herewith.

Also transmitted herewith is/are Form PTO-1449 (PTO/SB/08A and 08B) and copies of citations listed.

15. The above items are being transmitted before 30 months from any claimed priority date.

AUTHORIZATION TO CHARGE ADDITIONAL FEES

The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No.: 21-0800

37 C.F.R. Section 1.492(a)(1), (2), (3), and (4) (filing fees)

37 C.F.R. Section 1.17 (application processing fees)

37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a))

Date: 8/3/01

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PATENT
Docket No. IMPEL.57972

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	SIESS, Thorsten; FLAMENG, Willem	Examiner: Art Unit:
Int'l Appl No:	PCT/EP00/00863	
Int'l Filing Date:	03 February 2000	
Title:	A DEVICE FOR INTRAVASCULAR CARDIAC VALVE SURGERY	

I hereby certify that this correspondence is being deposited via First Class Mail in an envelope addressed to The Assistant Commissioner for Patents, Washington, D.C on August 3, 2001

By _____
Gunther Hanke, Reg No 32,989

Date of Signature: 8/3/01

Long Beach, California
August 3, 2001

PRELIMINARY AMENDMENT

BOX: PCT
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to the examination of the above-referenced patent application, please amend the claims as follows:

IN THE CLAIMS

Please substitute the following new claims:

8. A device for intravascular cardiac valve surgery, comprising:

a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14); and

a dilating device (18) surrounding the pump portion (14) wherein said dilating device is configured for breaking up a stenosis of a catheter valve upon deployment while positioned within said cardiac valve (AK).

9. The device of claim 8, characterized in that the pump portion (14) comprises a pump ring (15) and a tubular cannula (16) connected therewith.

10. The device of claim 8, characterized in that the dilating device (18) comprises an annular high-pressure balloon inflatable to at least 1.0 bar.

11. The device of claim 10, characterized in that the pump portion (14) comprises a pump ring (15) and a tubular cannula (16) connected therewith.

12. The device of claim 11, wherein the high-pressure balloon is seated on a rigid annular support.

13. The device of claim 10, wherein the high-pressure balloon is seated on a rigid annular support.

14. A device for intravascular cardiac valve surgery, comprising:

a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14);

a dilating device (18) for expanding a stent (21); and

a stent (21) carrying a folded flexible cardiac valve prosthesis (20) and being adapted to be expanded by the dilating device (17).

15. The device of claim 14, wherein the cardiac valve prosthesis (20) has a hose-shaped wall (24) that is folded together with a balloon wall of the dilating device (17).

16. The device of claim 14, wherein the cardiac valve prosthesis (20) is sewn to the stent (21).

17. The device of claim 16, wherein the cardiac valve prosthesis (20) has a hose-shaped wall (24) that is folded together with a balloon wall of the dilating device (17).

Please cancel original claims 1 - 7 without prejudice.

REMARKS

Claims 8 - 17 are pending.

Consideration of the application is respectfully requested.

If any additional fees are due with this paper, please charge our deposit account 21-0800.

Respectfully submitted,

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09/890778
JC05 Rec'd PCT/PTO 06 AUG 2001

A device for intravascular cardiac valve surgery

The invention refers to a device for intravascular cardiac surgery comprising a micro axial pump fastened to a catheter.

In WO 98/43688, an intra-cardiac blood pump is described that has a motor portion and a pump portion and can be introduced into the heart through the vascular system. Such a blood pump can be positioned in the aortal valve through the aorta, for example, to pump blood from the left ventricle into the aorta. Such blood pumps are adapted to support or replace the pumping effect of the heart. They can be positioned in the heart without requiring the heart to be opened.

From WO 97/37697, an intravascular blood pump is known that also has a motor portion and a pump portion, which are connected to a catheter. The blood pump can be pushed through the vascular system of the patient. It is a micro axial pump with a diameter of about 7 mm at most. The pump portion is surrounded by an expandable blocking device blocking the flow path outside the pump housing. Thereby, it is made sure that all blood drawn in is conveyed past the motor portion in the flow direction and short circuits caused by the flow around the pump portion are avoided. The blocking device may be an annular balloon affixed to the pump housing or an intake hose connected to the pump housing. This blood pump is intended for use in blood vessels, the blocking device only serving the purpose of blocking the vessel lumen around the pump portion, but not of deforming the vessel wall. Therefore, the balloon of the blocking device is a low pressure balloon inflated with low pressure so as to seal against the vessel wall in an non-traumatic manner.

Also known are dilating catheters having a balloon with which a vascular stenosis can be removed by pushing it open. Such dilating catheters can also be used to insert an annular stent consisting of an expandable metal structure and forming a supporting device, so as to form a permanent widening support for the stenosis. Such a dilating catheter is designed as a perfusion catheter

with a pump portion for conveying blood through the inflated balloon. For cardiac valve surgery, this dilating catheter is not suitable if only for its small diameter of 2 mm at most.

The most frequent defects of cardiac valves are valvular incompetence and valves with stenoses. In case of incompetence, the valve is unable to close fully. This causes a return flow. In general, such valves have to be replaced with artificial valves. Valves with stenoses have valve leaflets grown together at the edges, whereby the valve will not open completely and does not allow the full blood flow to pass therethrough.

There are two forms of surgery on the cardiac valves: In cardiac valve replacement, the natural cardiac valve is removed and surgically replaced with a bio-prosthesis or a mechanical cardiac valve. For this type of surgery, it is necessary to keep the operating area free from blood, i.e. to divert the natural blood flow. In case of a repair of the natural cardiac valve, a minimally invasive intervention can be performed using a balloon introduced into the valve. Such operations, e.g., at the aortal valve, the cardiac surgeon or the cardiologist needs great skill. Among others, the reason for this is that the blood flow through the aorta has to be blocked during the breaking process so that the operation has to be made in very short time for the supply to the vessel system to be restored. Further, the pressure inside the heart rises extremely when blocking the aortal flow while its blood supply via the coronal vessels is halted.

It is the object of the present invention to provide a device for intravascular cardiac valve surgery with which minimally invasive valve operations can be done relatively simple and without being pressed for time.

The object is solved, according to the invention, with the features of claim 1.

In the present device, an intravascular micro axial pump is provided, i.e., a pump that can be pushed through the vascular system of a patient and has an correspondingly small outer diameter that does not exceed 8 mm. The pump portion of the micro axial pump bears a dilating device which is adapted to break up a stenosis in a cardiac valve if placed in the cardiac valve. This dilating device preferably comprises a high-pressure balloon whose expanded diameter is at least 15 mm and which is inflatable with at least 1.0 bar. The high-pressure balloon is positioned in the cardiac valve and expanded using a liquid so that it breaks or blows open a stenosis in the cardiac valve. The dilating device thus forms an active element for breaking up a stenosis in a cardiac valve, in particular a stenosis in an aortal valve or a bicuspid valve.

The lumen of the pump portion or of the cannula adjoining the pump portion is at least 8 mm so as to avoid a too strong local blood flow with large physiological volume flows of up to 7 l/min. Further, the carrier of the dilating device should have an outer diameter of at least 8 mm so that a sufficiently large support for the dilating device is formed and the extent of the diameter increase does not become excessive.

Further, the invention refers to a device for intravascularly placing a cardiac valve prosthesis according to the features of claim 5. This device is also provided with a micro axial pump bearing a dilating device. Moreover, a stent is provided carrying a flexible cardiac valve prosthesis on its inner side. The stent containing the cardiac valve prosthesis can be introduced into the pathogenic cardiac valve and can be expanded by the dilating device so that it presses the valve leaflets of the natural cardiac valve apart. This cardiac valve prosthesis includes a single- or multi-wing cardiac valve that automatically becomes functional and replaces the natural cardiac valve.

As the cardiac valve prosthesis, a jugular valve taken from calves or cows can be used. This would be a bio-prosthesis of natural tissue.

The following is a detailed description of embodiments of the invention with reference to the drawing.

In the figures:

Fig. 1 illustrates a device for removing a stenosis in a cardiac valve, introduced into the aortal valve,

Fig. 2 shows the device of Fig. 1 with the dilating device expanded,

Fig. 3 is a longitudinal section of a flexible cardiac valve prosthesis,

Fig. 4 illustrates the cardiac valve prosthesis of Fig. 3 in combination with an expanded stent,

Fig. 5 is a cross-sectional view of the pump portion with a surrounding balloon as well as a stent with a cardiac valve prosthesis contained therein that is also folded,

Fig. 6 is a view of the device for implanting the flexible cardiac valve prosthesis, and

Fig. 7 shows the region of the heart with the implanted cardiac valve prosthesis in an aortal position.

Figure 1 illustrates a part of the heart, namely the left ventricle LV, from which blood flows through the aortal valve into the aorta AO. The aortal valve has three valve leaflets projecting into the aorta AO and forming a check valve in a fluidic sense that allows passage only into the aorta.

To push open an aortal valve AK with a stenosis, the device illustrated in Fig. 1 is introduced into the heart through the aorta. This device comprises a catheter 10 connected with a micro axial pump 40. The pump comprises a drive portion 11 including an electric motor and driving a shaft 12 protruding from the distal end of the cylindrical drive portion 11. A holding web 13 extends axially from the drive portion 11 to the tubular pump portion 14. The pump portion 14 comprises a pump ring 15 including an impeller wheel driven by the drive shaft 12, and a cannula 16 axially continuing the pump ring 15. The entire pump device, namely the drive portion 11 and the pump portion 14, has a maximum diameter of 8 mm. The catheter 10 comprises the electric wires for the supply and the control of the micro axial pump 40 and a pressure lumen through which pressure liquid can be supplied.

An annular balloon 17 is provided on the pump portion 14 and is illustrated in Fig. 1 in a folded state. Through the pressure lumen of the catheter 10, the balloon 17 may be inflated with liquid. The balloon is a high-pressure balloon with an inflated diameter of at least 15 mm, preferably between 15 and 40 mm, and resistant to pressures up to 8 bar. The balloon 17 extends over a pat of the length of the cannula 16. Its entire length may be supported by a rigid ring that prevents a compression of the cannula 16.

The pump device is introduced into the aorta by first placing a guiding wire (not illustrated) in the aorta and the left ventricle. Then the device is advanced along the guiding wire and positioned in the aortal valve AK such that the intake portion 16a is within the left ventricle LV, whereas the outlet portion 19 is within the aorta. The pump portion 15 is thus enclosed by the aortal valve AK. The pump device conveys backward, i.e., it draws axially and ejects laterally in the outlet portion 19.

After the pump device has been positioned in the way illustrated in Fig. 1, the drive portion 11 is activated so that the pump conveys blood from the

left ventricle LV into the aorta AO. Thereby, the heart is relieved in terms of volume and pressure and is calmed down. Then, the balloon 17 forming the dilating device 18 is inflated and expanded in the middle of the aortal valve AK. By the high-pressure inflated balloon 17, the valve leaflets of the aortal valve AK are pushed open and possible adhesions to the commissures are broken. In this manner a valve with a stenosis is pushed open far enough to reassume a completely open state. With the pump device, this form of valve operation can be performed in a calmed environment and without haste since, for the duration of the surgery, the cardiac output (l/min) is conveyed by the pump device through the dilating device. In a similar manner, the above described dilating device can be used to break open a natural bicuspid valve with a stenosis.

Figures 3 to 7 refer to a device with which an insufficient valve is replaced with a valve prosthesis. To this end, generally the same device as described with reference to Figures 1 and 2 is used. This device is illustrated in Figure 6. Situated on the deflated and folded dilating device 18 is a flexible cardiac valve prosthesis 20 above which a compressed spiral-shaped stent 21 is located.

Figure 6 further illustrates the guiding wire 22 that serves to advance the device with the catheter 10 and to place it in the correct position. The guiding wire 22 projects from the distal end of the cannula 16. It passes through a lateral hole 23 in the cannula and extends outside the pump portion 14 and the drive portion 11 along the catheter 10.

The flexible cardiac valve prosthesis 20 is illustrated in Figure 3. It is a bio-prosthesis that has been taken from a cow or a calf. For this purpose, a section 24 of a blood vessel including a vascular valve 25 was removed. This valve 24 may be a single-wing or a three-wing valve. According to Figure 4, this valve prosthesis 20 is placed within a stent 21. The stent 21 is a tubular element of metal rods which, in the present example, are bent meander-like and allow

for an axial compression or radial expansion. Other stent structures could also be used, such as, for example, a cell structure of stretch material. It is essential that the stent can reliably assume a compressed tubular shape and a n expanded tubular shape. The hose-shaped wall 24 of the vascular prosthesis 20 is sewed to the rods of the stent 21. Thus, the vascular prosthesis 20 is fastened to the inner side of the stent 21 so that after implantation of the vascular prosthesis, the stent rests between the natural cardiac valve and the bio-prosthesis and has no contact with the blood. Thus, the stent does not require the application of anti-coagulants against thrombosis.

Figure 5 illustrates the pump portion 14 with the pump ring 15. The balloon of the dilating device 18 and the valve prosthesis 20 are folded in a plurality of loops around the pump ring 15, the valve prosthesis being affixed to the rods of the stent 21. Int this state, the balloon, the valve prosthesis 20 and the stent 21 form a flat package surrounding the pump portion 14. This package is positioned in the natural cardiac valve AK. Thereafter, the pump is activated and the dilating device 17 is inflated with the pump operating. The stent 21 is dilated, widening the cardiac valve prosthesis 24 and pressing the leaflets of the natural aortal valve AK outward into the open position (systolic valve position, as illustrated in Figure 7. Thereby, the aortal valve AK is passivated. The stent 21 remains in the cardiac valve opening. In the stent, there is the cardiac valve prosthesis 24 enlarged to its original state and including the valve leaflets 25. This cardiac valve now assumes the function of the natural aortal valve AK.

To avoid displacement of the cardiac valve prosthesis, the stent 21 or the cardiac valve prosthesis 20 can be fixed in the annulus 26 surrounding the natural cardiac valve. This is a strong ring of cartilage suitable for use as a holder of a cardiac valve prosthesis.

Claims

1. A device for intravascular cardiac valve surgery comprising a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14), and a dilating device (18) surrounding the pump portion (14) which dilating device is suitable for breaking a stenosis of a cardiac valve when positioned in said cardiac valve (AK).

2. The device of claim 1, characterized in that the dilating device (18) consists of an annular high-pressure balloon inflatable with at least 1.0 bar.

3. The device of claim 1 or 2, characterized in that the pump portion (14) comprises a pump ring (15) and a tubular cannula (16) connected therewith.

4. The device of one of claims 1-3, wherein the high-pressure balloon sits on a rigid annular support.

5. A device for intravascular cardiac valve surgery comprising a micro axial pump (40) fastened to a catheter (10) and having a tubular pump portion (14), a dilating device (18) for expanding a stent (21), and a stent (21) carrying a folded flexible cardiac valve prosthesis (20) and being adapted to be expanded by the dilating device (17).

6. The device of claim 5, wherein the cardiac valve prosthesis (20) is sewn to the stent (21).

7. The device of claim 5 or 6, wherein the cardiac valve prosthesis (20) has a hose-shaped wall (24) that is folded together with a balloon wall of the dilating device (17).

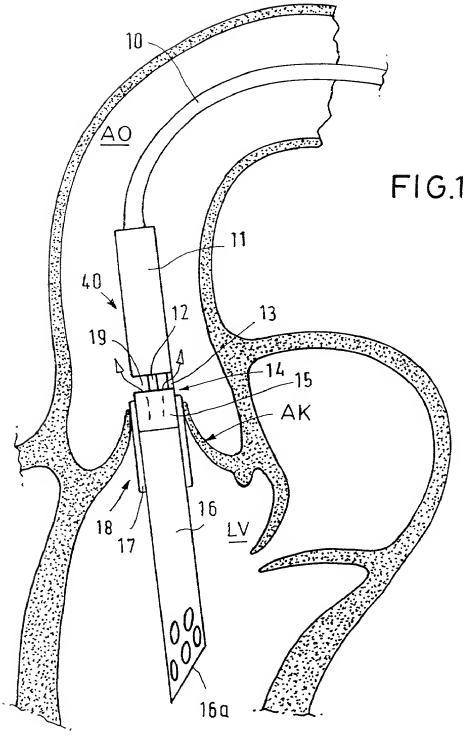

FIG.1

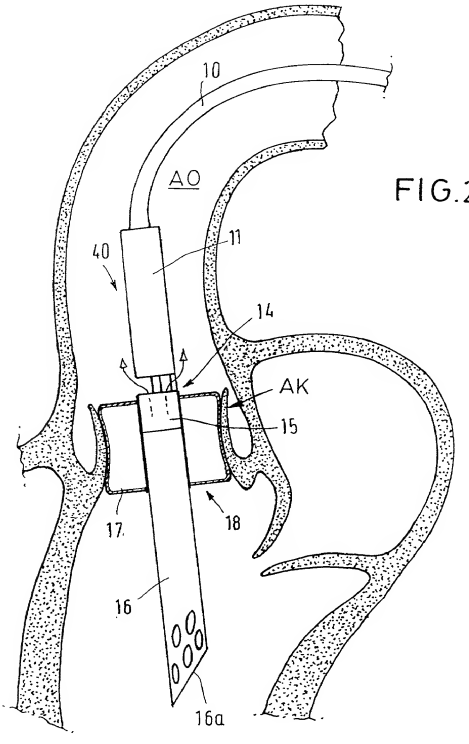

FIG.2

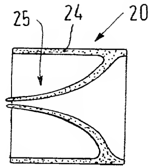

FIG.3

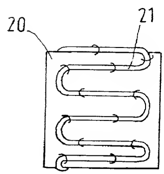

FIG.4

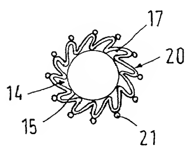

FIG. 5

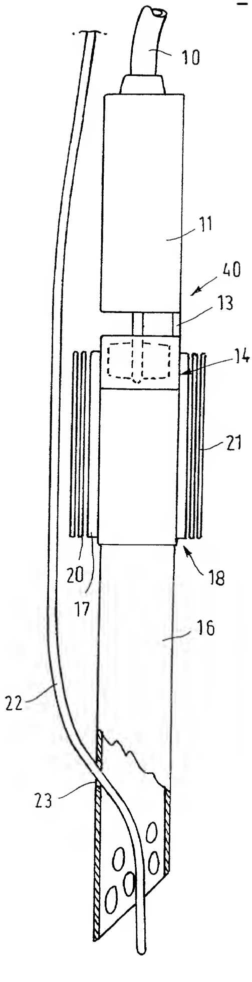

FIG.6

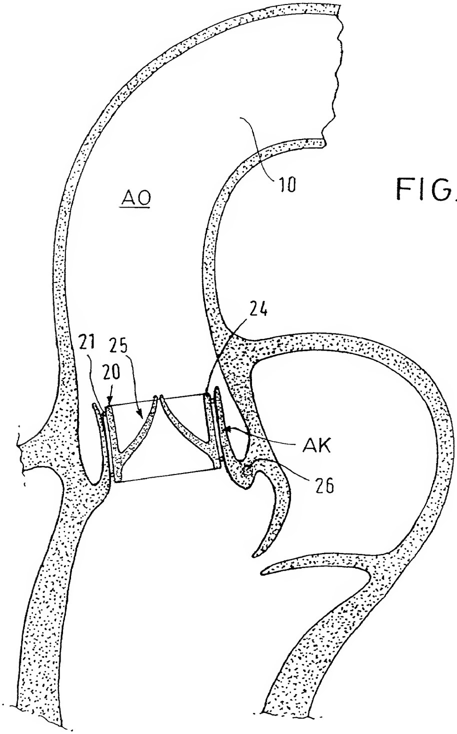

FIG.7

I hereby appoint the following attorneys to prosecute this application and/or an international application based on this application and to transact all business in the Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the attorneys identified below, unless the inventor(s) or assignee provides said attorneys with a written notice to the contrary:

GUNTHER O. HANKE

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor. Insert Name of Inventor Insert Date This Document is Signed. Insert Residence Insert Citizenship. Insert Post Office Address.

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Full Name of Fourth Inventor, if any: see above

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CITIZENSHIP:

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Full Name of Fifth Inventor, if any: see above

GIVEN NAME	FAMILY NAME	INVENTOR'S SIGNATURE	*DATE

RESIDENCE (City, State & Country):

CITIZENSHIP:

POST OFFICE ADDRESS (Complete Street Address including City, State & Country):

*Note: Must be completed — date this document is signed.

USPTO Approved 3-90)
Revised 7-93)

PCT/EP00/00863
USA

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

ATTORNEY DOCKET NO.

As a below named inventor, I hereby declare that: my residence post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: *

Insert Title

A device for intravascular cardiac valve surgery

Check Box If Appropriate — For Use Without Specification Attached

the specification of which is attached hereto unless one of the following boxes is checked:

☐ The Specification was filed on _____ and was assigned Serial No. _____ and was amended on _____

☒ was filed as PCT international application number PCT/EP00/00863 on February 3, 2000 and was amended under PCT Article 19 on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows:

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below:

Insert Priority Information (If appropriate)

Prior Foreign Application(s)			Priority Claimed	
199 04 975.0 (Number)	Germany (Country)	February 6, 1999 (Month/Day/Year Filed)	☒ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More Than 12 Months (6 Months for Designs) Prior To The Filing Date of This Application:

Country	Application No.	Date of Filing (Month/Day/Year)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status — patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status — patented, pending, abandoned)

*NOTE: Must be completed.